UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,859	07/30/2003	Gary F. Gerard	0942.5530002/RWE/HCC	6152

26111 7590 09/05/2006

STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER	
BURKHART, MICHAEL D	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,859	GERARD, GARY F.	
	Examiner	Art Unit	
	Michael D. Burkhart	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-17,19-22,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-17,19-22,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt and entry of the amendment dated 6/21/2006 is acknowledged. After entry of the amendment, claims 9-17, 19-22, 25 and 26 are pending and under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-17, 19-22, 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection necessitated by amendment of the claims.**

Amended claims 9, 13 and 19 (from which all other claims depend) have been amended to recite compositions and methods comprising "dNTPs in excess of one or more degradation components." The response does not indicate where in the specification support for the amendment is to be found. As amended, the claims encompass a broad genus of compositions and methods wherein dNTPs are in excess of any "degradation component", which, as defined in the specification, may be "a compound, molecule, or protein ... capable of RNA degradation or cleavage" (see ¶ [0043] of the published application, US 20040152072 A1, cited in the attached PTO-892). A reading of the specification reveals the only case wherein dNTPs are contemplated to be used in excess of a "degradation component" is wherein dNTPs are 1mM in excess of Mg^{+2}

(e.g. ¶ [0154]). This single example does not provide support for the broadly claimed genus of compositions and methods wherein dNTPs are in excess of any degradation component. Furthermore, regarding the Mg^{+2} example, the range of Mg^{+2} concentrations embraced by the claims includes embodiments wherein Mg^{+2} is not even present in the composition or method, or wherein the concentration of Mg^{+2} is too low such that the compositions have no utility in reverse transcriptase (RT) assays, or the method claims will not work (either Mg^{+2} or Mn^{+2} are a necessary ingredient in RT reactions, typically in the mM range for an efficient reaction, see ¶ [0018] and the prior art of record). Therefore, there appears to be no support for compositions or methods wherein "dNTPs in excess of one or more degradation components" are used, and no evidence that applicants considered such as their invention. Thus, the amended claims include impermissible New Matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-17, 19-22 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwabe (1998, of record).

Claims 9-17, 19-22 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Gerard (1997, of record).

Claim 9, 25, and 26 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention as evidence by Gibco (Gibco BRL 1997/1998 Products & Reference Guide, of

record). This rejection is applied to claims 9 due to amendment of the claims. Claim 9 reads on purified dNTPs because, absent evidence to the contrary, the purified dNTPs do not comprise a degradation component. Furthermore, there is no Mg^{+2} in the purified dNTPs, hence they are in excess of Mg^{+2}.

The above rejections are maintained for reasons made of record in the previous Office Action and for reasons outlined below.

Response to Arguments

Applicant's arguments filed 6/21/2006 have been fully considered but they are not persuasive. Applicants' arguments regarding the above rejections are essentially the same, hence they will be addressed together. Applicants assert that the claims have been amended to recite compositions and methods wherein dNTPs in excess of one or more degradation components are used, and that none of the prior art references cited above teach this limitation. However, the definition of "degradation component" in the specification is broad (as noted above) and encompasses, at the least, RNase enzymes, which degrade RNA. RNase contamination of RT reactions is a common problem when RNA is isolated from eukaryotic cells, and bacterial RNases can be a problem in buffers, plastic ware, etc. For example, Schwabe et al use the commercial RNase inhibitor "RNaseOUT" in their first strand synthesis reactions (i.e. a RT reaction, see page 30, second column). The documentation for RNaseOut (Invitrogen, 2001) indicates its utility in RT-PCR and cDNA synthesis reactions, and that it inhibits many eukaryotic RNases. Likewise, Gerard et al underscore the importance of inactivating RNases during preparation of RNA (page 64, first column, first ¶). In any event, the level of RNases in

the teachings of the above references is, absent evidence to the contrary, less than 4mM, i.e. the concentration of dNTPs used in Schwabe et al and Gerard et al. This is because the RNA used is initially purified from eukaryotic cells (e.g. see page 30, first column of Schwabe et al) and thus the concentration of RNases is greatly reduced, if not eliminated. Secondly, even if some RNase managed to contaminate the RT reactions, it could not be close to a concentration of 4 mM (i.e. the concentration of dNTPs). This is because, based on the molecular weight of a representative RNase from human pancreas (15 Kd, as taught by Russo et al, 1993, page 234, second column, first full ¶), 4 mM of an RNase would represent 6 mg of RNase in a 100 ul reaction. If the levels of RNase were indeed this high, it is argued that no RNA would be present in the RT reaction, as it would be degraded by such a high level of RNase. Thus, it is considered that the above references teach the use of dNTPs in excess of RNase, a degradation component.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

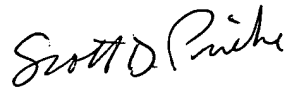
CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael D. Burkhart
Examiner
Art Unit 1633



SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER